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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,763 | 11/02/2001 | Isaiah J. Fidler | UTSC:684US/SLH | 2999 |

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FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

| EXAMINER | |
|---|---|
| UNGAR, SUSAN NMN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/010,763 | FIDLER ET AL. | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-14 and 34-42* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3,8-14,34-41 and 43* is/are rejected.

7)☐ Claim(s) *37-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3.14.2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed March 14, 2005 in response to the Office Action of November 9, 2004 is acknowledged and has been entered. Claims 15-33 have been canceled, Claim 1 has been amended and Claims 34-43 have been added. Claim 42 as well as all limitations drawn to growth factor receptor phosphorylation other than EGFR phosphorylation in the newly added claims have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected inventions. Further, upon review and reconsideration, the limitations of claims 14 and 43 drawn to cancers of the breast, brain, lung, ovary have been rejoined with the invention under prosecution given the teaching of Pollack et al, wherein each of these cancer types overexpress EGFR. Claims 1-3, 8-14, 34-41, 43 are currently under prosecution.

2. Since applicant has elected Group I drawn to EGFR phosphorylation assay wherein EGFR is a tyrosine kinase receptor for action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of claim 42 directed to assay of a serine threonine kinase receptor and limitations drawn to any receptor other than EGFR have been withdrawn from consideration as being directed to non-elected inventions and only claims as they are drawn to EGFR will be examined. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03. Newly submitted claims drawn to receptors other than EGFR are independent or distinct from EGFR for the reasons previously set forth. Further, serine threonine kinase receptors, in particular, are independent or distinct because they differ structurally and functionally from EGFR and are made by and used in different methods than EGFR.

3. Applicant points out that Examiner incorrectly failed to consider claim 3 which is a specific part of the Group 1 invention elected August 30, 2004. Although it is clear

that Examiner did not include claim 3 in the rejections of record, it is hereby noted that Examiner did consider claim 3, but through an inadvertent typographical error, neglected to include claim 3 in the rejection under 35 USC 112, first paragraph in Section 4, pages 2-5 of the action. Examiner apologizes for any inconvenience caused by this omission and in order to make the record clear will formally reject claim 3 under 35 USC 112, first paragraph in this action for the reasons of record and make the action non-final so that Applicant has an opportunity to traverse the rejection of claim 3.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following rejections are maintained:

***Claim Rejections - 35 USC § 112***

6. Claims 1-2, 8-14 remain rejected and claims 3 and 34-41, 43 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed November 9, 2004, Section 4, pages 2-5.

Applicant argues that claim 1 is now directed to cancer treatments that are designed to change growth factor receptor phosphorylation which should address the Examiner's concerns. Applicant argues that claim 1 does not require that the cancer necessarily be growth factor positive because physicians are the ones that will make the decision about the applicability of a particular treatment and if the treatment is designed to change growth factor receptor phosphorylation, then presumably the physician has concluded that the cancer is one that is likely growth factor related and the assay will necessarily and inherently make the determination that the cancer is growth factor related if indeed it is.

The argument has been considered but has not been found persuasive because the amendment of the claims does not address the issue raised drawn to assaying for the

effectiveness of a cancer treatment wherein the cancer expressed growth factor receptor/EGFR prior to treatment. In particular, as previously set forth, the specification repeatedly teaches that according to the invention, a sample of growth factor receptor/EGFR expressing cells is collected from the patient suffering from a form of cancer which is known to overexpress EGFR prior to treatment and the level of phosphorylation is determined and for the very clear reasons raised previously, the claims are not enabled. Although Applicant argues that physicians make the decision about the applicability of a particular method for determining the effectiveness of a cancer treatment it is not within the purview of said physicians to determine the enablement of the claims. Further although Applicant argues that the assay will necessarily and inherently make the determination that the cancer is growth factor related if it is, this is not persuasive since the claims are not drawn to determining whether a cancer is growth factor related, but rather is drawn to determining the effectiveness of a cancer treatment and for the reasons of record, the claims are not enabled. In addition, it is noted that the amendment to the claims does not address the issue raised drawn to assaying receptor phosphorylation of the receptor specifically targeted by the cancer treatment. The argument is not found persuasive and the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC 112***

7. Claims 1-3, 8-14, 34-41, 43 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a non-tumor surrogate tissue sample recited in claim 1, in the absence of the modifier "from skin/hair follicles" has no clear support in the specification and the claims as originally filed. Applicant points to support for the claim amendment on page

60, line 67. However, since page 60 does not have a line 67, a review of the published application reveals support for the term "surrogate" at paragraph 0227. The specification teaches that the expression of phosphorylated EGF-R in skin/hair follicles parallels that of tumors. Determination of phosphorylated EGF-R in skin/hair follicles can therefore serve as a surrogate for tumors. However, a further review of the published application reveals no other disclosure of the term "surrogate". The suggested support is not found persuasive because the specification neither provides guidance on nor contemplates any surrogate other than skin/hair follicles. Thus, the subject matter claimed in claims 1-3, 8-14, 34-41, 43 broadens the scope of the invention as originally disclosed in the specification.

8. Claims 1-3, 8-14, 35-37, 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method wherein the cancer treatment is designed to inhibit growth factor receptor phosphorylation, does not reasonably provide enablement for the claimed method wherein the cancer treatment is designed to change growth factor receptor phosphorylation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method for determining the effectiveness of a cancer treatment comprising obtaining a non-tumor tissue surrogate tissue sample from a patient undergoing cancer treatment wherein the cancer treatment is designed to change growth factor receptor phosphorylation. This means increasing phosphorylation as specifically claimed in claim 35 as well as inhibiting phosphorylation. The specification teaches, at paragraph 0021 of the published application, that the cancer treatment that the patient is undergoing can be one which results in changes in growth factor receptor phosphorylation and that the change can be a decrease or an increase in the growth

factor receptor phosphorylation. The specification further teaches that chemotherapeutic drugs typically used to treat cancers and their metastases are those that inhibit phosphorylation of the growth factor receptors (p. 2, lines 25-31). However, no other teaching or guidance is provided as to cancer therapies which result in changes in growth factor receptor phosphorylation and which cancer therapies increase growth factor receptor phosphorylation such that this activity could be assessed by the claimed method with a reasonable expectation of success. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that one could practice the claimed broadly claimed method with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

***Claim Objections***

9. Claim 37-42 are objected to because claim 37 is dependent upon claim 38 and claim 38 is dependent upon claim 37. It appears that there has been a typographical error and that claim 37 was meant to be dependent upon claim 1. Appropriate correction is required.

10. All other objections and rejections imposed in the Paper mailed November 9, 2004 are hereby withdrawn.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (571)-273-8300.

Susan Ungar,
Primary Patent Examiner
May 27, 2005